

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

GE HEALTHCARE BIO-SCIENCES AB, GE
HEALTHCARE BIO-SCIENCES
CORPORATION, and GENERAL ELECTRIC
COMPANY,

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

Civil Action No. 14-CV-7080

Hon. Laura Taylor Swain

DECLARATION OF CARL SCANDELLA, Ph.D.

1. My name is Carl Scandella. I have been retained as an expert on the behalf of Plaintiffs GE Healthcare Bio-Sciences AB, GE Healthcare Bio-Sciences Corp., and General Electric Company (collectively, “GE”) to provide opinions regarding the infringement of U.S. Patent No. 8,821,718 (the “718 patent”), which is currently asserted by GE against Bio-Rad Laboratories, Inc.’s (“Bio-Rad”) NGC system.

2. The bases for my conclusions include the following: (a) my experience of more than thirty years in the relevant chromatography systems; (b) my review of the documents pertaining to this litigation; and (c) my investigation of the NGC system.

I. BACKGROUND AND QUALIFICATIONS

3. I received a Ph.D. in Biochemistry from Stanford University School of Medicine and a B.S. in Chemistry from the California Institute of Technology. I am the owner of Carl Scandella Consulting, a firm that has provided consulting services since 1992 to over 45 clients in the areas of biomolecule purification and analysis, process development, and manufacture of

clinical lots. I have also lectured and taught courses in pharmaceutical biotechnology and protein purification for university and industry groups in the United States, Europe, and Japan. I have lectured and served as a Visiting Scholar at the University of Washington and am currently a Science Education Advisor at the Pacific Science Center in Seattle, Washington. My curriculum vitae is included as **Exhibit A**.

4. Prior to starting Carl Scandella Consulting, I was a Senior Scientist at Chiron Corporation in Emeryville, California. At Chiron, I was a charter member of the Manufacturing and Process Development Division Senior Staff, managed the Manufacturing Protein Purification and Process Development Groups, developed purification processes and supervised purification of more than seventy lots of several products under cGMP. Prior to Chiron, I was a Principal Scientist of Protein Chemistry at Genex Corporation, a biotechnology company in Maryland. At Genex, I discovered and patented novel methods for solubilizing, renaturing, and purifying recombinant enzymes from inclusion bodies. I have been issued several patents by the United States Patent and Trademark Office, including Patent No. 5,614,612 ("Purified gp120 Compositions Retaining Natural Conformation"); No. 4,721,673 ("Recovery and Activation Process for Microbially Produced Calf Prochymosin"); and No. 7,071,313 ("Method For Purifying Authentic IGF-1 From Yeast Hosts").

5. Prior to joining Genex, I was an Assistant Professor of Biochemistry at SUNY Stony Brook University in New York for six years. As a professor, I taught undergraduate, graduate, and medical school courses, trained M.S. and Ph.D. students, and received research grant support from the National Institute of Health and National Science Foundation for studies of cell membranes and membrane proteins. I was also a Cystic Fibrosis Foundation Postdoctoral Fellow at the University of Basel in Switzerland, a National Science Foundation Postdoctoral

Fellow in the Department of Chemistry at Stanford University, and I received a grant from the Centre National de la Recherche Scientifique in France for research at the Pasteur Institute in Paris.

6. My fields of expertise include chromatography and protein purification; scale-up and manufacture of new biopharmaceutical products including therapeutics, vaccines, diagnostics and medical devices; and development and application of new technologies for purification and analysis. I have published in leading academic journals in the biotechnology areas, including the *Journal of Bacteriology*, *Biochemistry*, *Journal of Biological Chemistry*, *Proceedings of the National Academy of Sciences USA*, *Science*, *Nature*, *Biotechnology*, *Experimental Cell Research*, and *Journal of Virology*, among others. I have also contributed to publications on chromatography, including *Introduction to Modern Liquid Chromatography*, Third Edition (2010), and *Gradient Elution Chromatography* (2007), and have for many years worked closely with Dr. Lloyd Snyder, who co-authored these publications and is considered a pioneer in the field of liquid chromatography.

7. I am being compensated for my time in consulting for this case at my customary rate of \$400 per hour. My compensation is not contingent upon my testimony or the result of this proceeding. **Exhibit B** provides a list of the documents considered.

II. THE '718 PATENT.

8. The '718 patent is titled "Automated Fluid Handling System." It was filed on June 4, 2010 and issued on September 2, 2014. The '718 patent lists Johan Blomberg and Mats Lundkvist as the inventors.

9. I understand that GE intends to file a preliminary injunction motion against Bio-Rad asserting that Bio-Rad infringes independent claims 1 and 16 and dependent claims 2, 3, 5, 11, 14, 17, and 18 of the '718 patent.

III. LEGAL STANDARDS APPLIED IN THIS DECLARATION

10. I understand that the following legal standards apply to my analysis presented in this declaration.

11. I have been advised by counsel for GE that analysis of a patent infringement involves two steps: (a) properly construing the patent claims to ascertain their scope and meaning; and (b) comparing the properly construed claims with the accused product.

12. I understand that the first step in any infringement analysis is to determine the scope of the claims at issue, and that such "claim construction" is a legal matter to be decided by the Court.

13. I understand that the Court has not yet construed any disputed claim terms in this litigation. Therefore, I expressly reserve the right to supplement my opinions and this report following any claim construction by the Court.

14. I understand that the claims delineate the bounds of a patentee's invention and that claim construction starts with the language of the claims. I further understand that claims are interpreted from the standpoint of a person of ordinary skill in the art in light of the patent specification, its prosecution history, and any relevant extrinsic evidence.

15. My understanding is that patent infringement is determined according to 35 U.S.C. § 271, which states that "whoever without authority makes, uses, offers for sale, or sells any patented invention, within the United States, or imports into the United States any patented invention during the term of the patent therefore, infringes the patent."

16. GE's counsel further has advised me that there are two types of direct infringement: literal infringement and infringement under the doctrine of equivalents.

17. I understand that to prove direct infringement of an asserted claim, GE has the burden to prove by a preponderance of the evidence that the NGC system infringes an asserted claim either literally or under the doctrine of equivalents.

18. I understand that for GE to prove that Bio-Rad has literally infringed an asserted claim, GE must prove by a preponderance of the evidence that each and every limitation set forth in that asserted claim is present in the accused system. I understand that each claim is evaluated separately, but each limitation of a claim must be present in the accused method for that claim to be infringed. If even a single element is missing, there is no infringement.

19. I was advised that even if literal infringement is lacking, infringement under the doctrine of equivalents may still apply. As with literal infringement, for infringement to be found under the doctrine of equivalents, the accused product must include an equivalent element for every element in the claims that is not literally present in the accused product. I understand that an element in an accused product is equivalent to a claim limitation when the difference between the two is "insubstantial." One test for determining whether a difference is "insubstantial" is the triple identity test. Under that test, an element in an accused product is insubstantially different from a claim limitation where it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claim limitation.

IV. LEVEL OF SKILL IN THE ART

20. I understand that under the doctrine of equivalents, evidence of equivalence must be from the perspective of a person of ordinary skill in the art.

21. I understand that claims are construed from the perspective of one of ordinary skill in the art to which the patented subject matter pertains at the time of the invention.

Furthermore, I understand that a determination of the level of ordinary skill in the art includes as relevant factors (1) the educational level of the inventor; (2) the type of problems encountered in the art; (3) the prior solutions to those problems; (4) the rapidity with which innovations are made in the art; (5) the sophistication of the technology in the art; and (6) the educational level of active workers in the field.

22. The invention of the '718 patent generally relates to an automated fluid handling system, more specifically a liquid chromatography system, a filtration system, a chemical synthesis system or the like. In my opinion, and based on the above factors, a person of ordinary skill in the art at the time of the invention is an individual who has a scientific or technical background and at least a few years of experience in the design, operation and/or use of automated fluid handling systems such as liquid chromatography systems, filtration systems, chemical synthesis systems or the like.

23. As discussed above, and in my Curriculum Vitae, I have the requisite education and extensive experience in this field, and therefore qualify as one of skill in the art.

V. THE ACCUSED PRODUCT -- THE NGC SYSTEM

24. Bio-Rad makes and sells the NGC system.

25. I have inspected and used the NGC system in a laboratory setting. True and correct copies of photographs I took during my inspection of the NGC system are included as figures throughout this declaration (except for Figures 71(a) and 71(b), which are images from an "NGC System Tour" available at <http://biorad-ads.com/ngc-interactive-demo/>). I also have reviewed certain of Bio-Rad's instructional and marketing materials, including the NGC

Instrument Guide v. 1 and the NGC Chromatography Systems Module Selection Guide, true and correct copies of which are attached as **Exhibit C** (NGC Instrument Guide v. 1) and **Exhibit D** (NGC Chromatography Systems Module Selection Guide).

VI. DEPENDENT AND INDEPENDENT CLAIMS

26. I understand that a claim in dependent form shall be construed to incorporate by reference all the limitations of the independent claim to which it refers. Accordingly, I understand that in order to infringe a dependent claim, the accused product must meet all the claim limitations of the dependent claim, in addition to the claim limitations of the independent claim to which it refers.

VII. OPINIONS AND BASES FOR OPINIONS

27. Given the legal standards explained to me by counsel for GE and my analysis of the NGC system as set forth above, it is my opinion that the NGC system directly infringes, either literally or under the doctrine of equivalents, independent claims 1 and 16 and dependent claims 2, 3, 5, 11, 14, 17, and 18 of the '718 patent. I set forth below the bases for my opinion in regard to the accused product and each claim.

A. Claim 1 of the '718 Patent

28. Claim 1 of the '718 patent is an independent claim.

Preamble

Automated fluid handling system comprising

Evidence of Infringement

29. I have reviewed Bio-Rad's instructional and marketing materials, which show that the NGC system is an automated fluid handling system in the form of a liquid chromatography

system. *See, e.g.*, NGC Instrument Guide v.1 p. 9. This is consistent with my inspection of the system.

30. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(a):

a housing and two or more interchangeable fluid handling units the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units

Evidence of Infringement

31. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the NGC system comprises a housing that has bays into which two or more modular fluid handling units are inserted. *See, e.g.*, NGC Instrument Guide v.1 p. 15 ("The modular components slide into slots in the system known as bays."); *id.* p. 18 (showing the housing and multiple modular fluid handling units). This is consistent with my inspection of the system.

32. The housing includes a "liquid handling panel," which is the front panel of the bays in the housing of the NGC system. *See, e.g.*, Fig. 42; NGC Instrument Guide v.1 at pp. 18, 187-190. The bays define various component positions for receiving the modular fluid handling units/modular components. For example, the modular components of the NGC system include a system pump, a conductivity detector & a UV detector (the conductivity detector and UV detector are mounted in the same module in the NGC system I examined), an inject valve, a mixer, and a sample inlet valve. *See id.* at p. 19, 33, 51. These modular components are fluid handling units because fluid flows through the external fluidics section of each module. *See, e.g.*, NGC Chromatography Systems Module Selection Guide p. 4 (NGC system capabilities

schematic showing fluid flow through various modules, including system pumps), p. 8 (showing fluid flow through UV detector module and conductivity monitor); NGC Instrument Guide v.1 p. 23 (showing fluid flow through various modules, including inject valve, conductivity monitor, and system pumps), p. 51 (explaining that the mixer is located between two system pumps so that flow from the pumps enters and exits the mixer).

33. The modular fluid handling units/modular components are interchangeable. *See, e.g.,* NGC Instrument Guide v.1 at 15. (“The position of each module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume.”).

34. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(b):

wherein said units are arranged as interchangeable modular components, and include:

Evidence of Infringement

35. I have reviewed Bio-Rad’s instructional and marketing materials, and I have inspected the NGC system, and I have determined that the liquid handling units of the NGC system are modular components that slide into the bays of the housing. *See, e.g.,* NGC Instrument Guide v.1 at p. 15 (“The modular components slide into slots in the system known as bays.”). The illustration of the housing of the NGC system shows the principle of interchangeable modules fitting into bays. *See, e.g., id.* at p. 186. Figure 35 below also illustrates a modular component fitting into a bay.

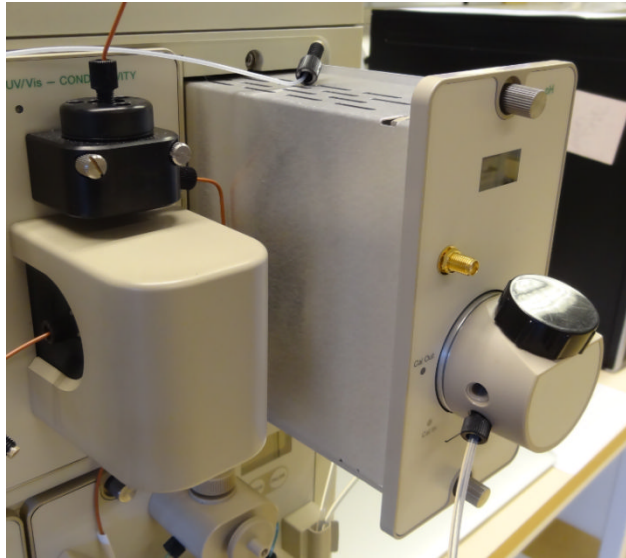


Fig. 35

36. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(c):

a fluidics section;

Evidence of Infringement

37. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include fluidics connections for various components that include fluidics on the outside of the respective panels of each component. *See, e.g.,* NGC Instrument Guide v.1 pp. 19-74. For example, the NGC system has two system pumps, a UV detector/conductivity monitor, and a sample pump that are interchangeable modular components and which contain fluidics sections on the exterior portion of the module. *See* NGC Instrument Guide v. 1 pp. 18-19, 24-25, 54-61.

38. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(d):

a non fluidics section comprising electronics or electrical components or control means;
and

Evidence of Infringement

39. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include a non fluidics section of electronics or electrical components on the side of the modular component that is inserted into the bay. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74, 186. As shown in Figure 39(a) below, the back of each module has electronics and electrical components on the back side that plug into the housing.

*Electronics/electrical
 components*

Alignment post

*Electronics/electrical
 components*



Fig. 39(a)

The alignment post next to each of the electronics and electrical components (*see* Figure 39(a), above, showing the back of the single wavelength UV/conductivity module) aligns the electronics and electrical components with receptacles in the housing (shown in Figure 39(b), below). *See also* NGC Instrument Guide v.1 pp. 188-189. This illustrates that the electronics

and electrical components are on the side of the modular component that is inserted into the bay (as opposed to the front-facing side, which contains the fluidics section -- *see, e.g.*, Fig. 41).

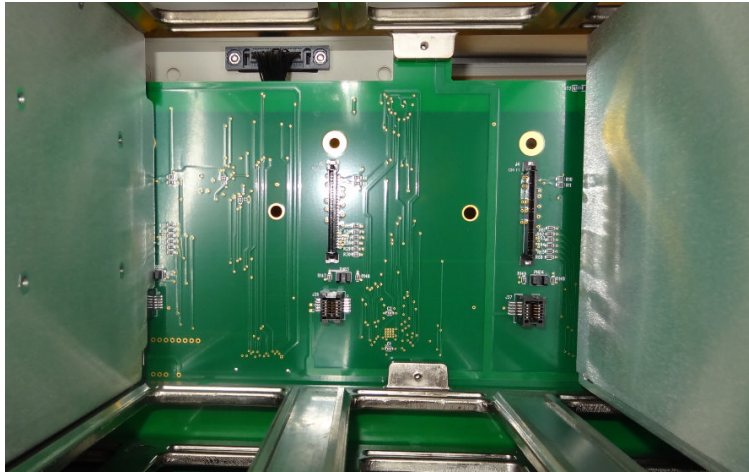


Fig. 39(b)

40. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(e):

a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,

Evidence of Infringement

41. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include a panel that separates the external fluidics section from the internal non fluidics section. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74, 186. Specifically, and as shown in Figure 41 below, each NGC module is provided with a front facing physical barrier that provides a separation between the external fluidics and the internal non-fluidics components of the modular component. *See also* NGC Instrument Guide v.1 p. 188.

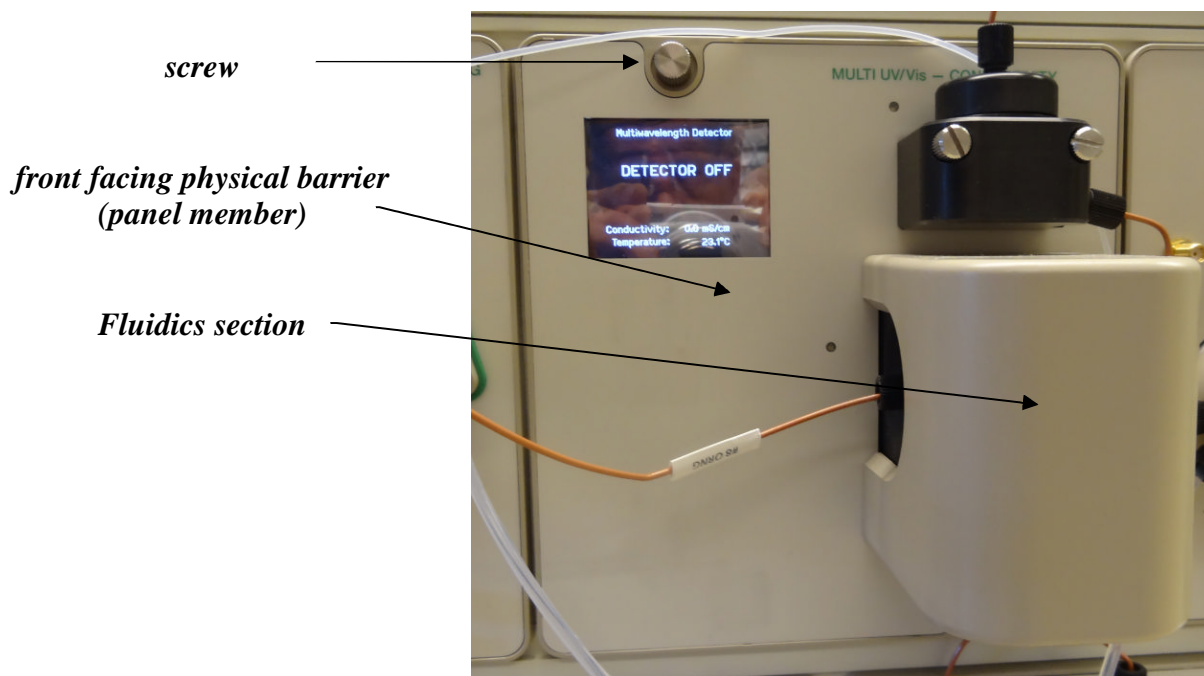


Fig. 41

42. The panel member also provides for attachment of the modular component to the liquid handling panel. Specifically, the panel member contains a screw or screws (shown in Figure 41 above) which, when tightened, attach the modular component to the liquid handling panel (shown in Figure 42 below). *See also* NGC Instrument Guide v. 1 pp. 187-188



Fig. 42

43. Thus, I have concluded that the NGC system satisfies this claim element.

Element 1(f):

and wherein the two or more component positions of the liquid handling panel are arranged for attachment of the panel members such that said respective non fluidics sections are internal to the housing.

Evidence of Infringement

44. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the liquid handling panel contains two or more component positions arranged such that panel members are attached to the liquid handling panel. This is illustrated in Figure 42 (above), which shows a double wide bay with two component positions of the liquid handling panel with screw holes at the bottom of each position for attachment of the panel members. *See also* NGC Instrument Guide v.1 pp. 188-190 (explaining, among other things, that the double-wide bay can be converted into a single-wide bay for placement of two single-wide modules).

45. When at least two panel members are attached at the component positions of the liquid handling panel -- *e.g.*, the front panel of the bays in the housing of the NGC system -- the non fluidics sections are internal to the housing. *See* Fig. 42; *see also* NGC Instrument Guide v.1 at p. 187-190.

46. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 1 of the '718 patent

47. Because the NGC system meets all the limitations of Claim 1 of the '718 patent, it is my opinion that the NGC system infringes Claim 1 of the '718 patent.

B. Claim 2 of the '718 Patent.

48. Claim 2 of the '718 patent depends from Claim 1. It is my understanding that this means that all of the elements recited in Claim 2 are added to what is recited in Claim 1. As such, the bases provided above that demonstrate that the NGC system infringes Claim 1 apply equally here.

Preamble

The fluid handling system of claim 1,

Evidence of Infringement

49. The NGC system meets all the elements of Claim 1, as discussed above.

Element 2(a):

wherein the interchangeable modular components are sealed against the liquid handling panel by a sealing member.

Evidence of Infringement

50. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and, as discussed above, I have determined that the modular

components of the NGC system include a panel member or physical barrier that separates the external fluidics section from the internal non fluidics section, and which allows the component to be secured to the liquid handling panel of the housing. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74, 186; Fig. 41. Each NGC module is also provided with a seal, which acts as a “sealing member” to provide a sealed separation between the external fluidics and the internal non-fluidics parts at the liquid handling panel, as illustrated in Figure 50, below.

Sealing member providing sealed separation between external fluidics and internal non fluidics sections

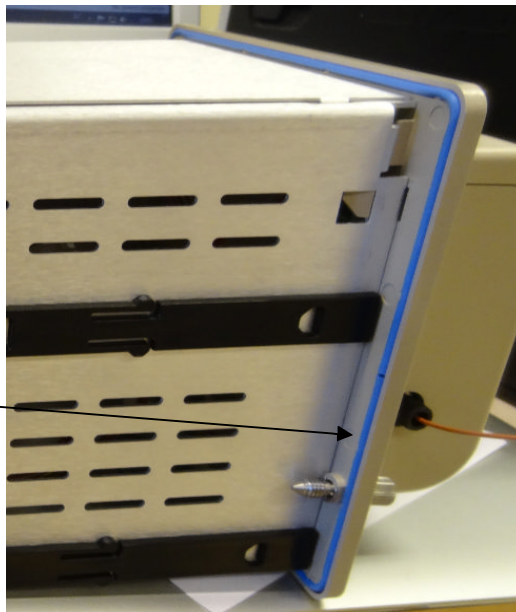


Fig. 50

51. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 2 of the '718 patent

52. Because the NGC system meets all the limitations of Claim 2 of the '718 patent, it is my opinion that the NGC system infringes Claim 2 of the '718 patent.

C. Claim 3 of the '718 Patent.

53. Claim 3 of the '718 patent depends from Claim 1. It is my understanding that this means that all of the elements recited in Claim 3 are added to what is recited in Claim 1. As

such, the bases provided above that demonstrate that the NGC system infringes Claim 1 apply equally here.

Preamble

The fluid handling system of claim 1,

Evidence of Infringement

54. The NGC system meets all the elements of Claim 1, as discussed above.

Element 3(a):

comprising a master control unit

Evidence of Infringement

55. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that a computer is used to run the NGC system and act as a "master control unit." *See, e.g.,* NGC Instrument Guide v.1 p. 72. The computer, also shown in Figure 55 below, is used to perform system control functions. *See* NGC Instrument Guide v. 1 p. 72.

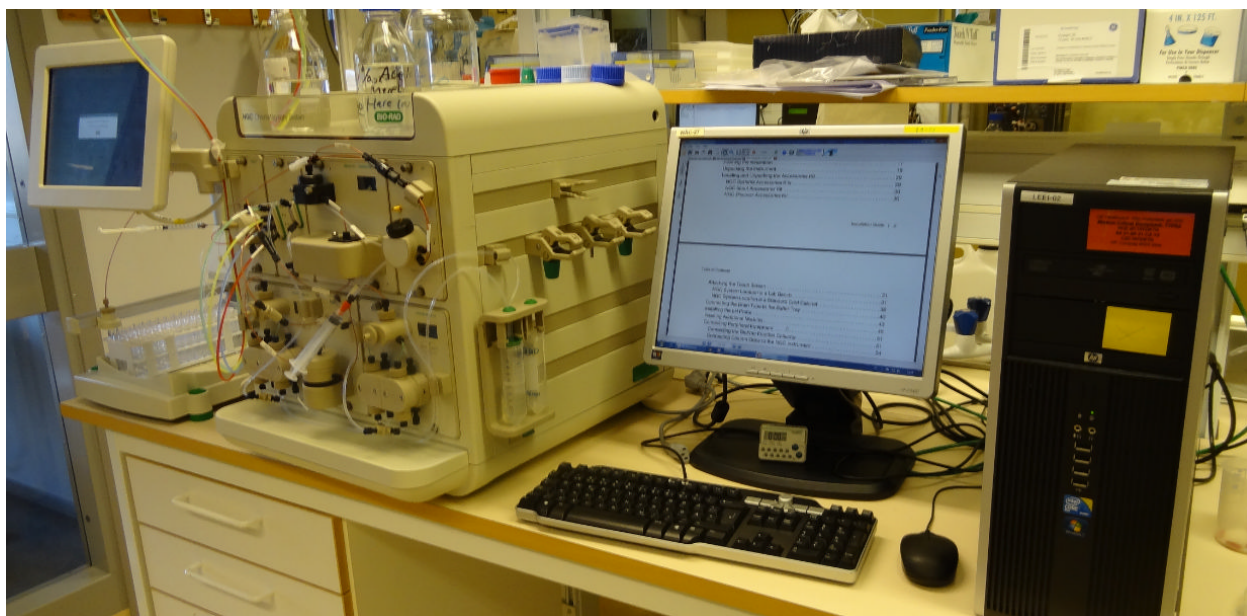


Fig. 55

56. Thus, I have concluded that the NGC system satisfies this claim element.

Element 3(b):

wherein the interchangeable modular components are connected to the master control unit by a system bus providing electrical communication to each interchangeable modular component.

Evidence of Infringement

57. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that a connector card connects each modular component to the computer that runs the NGC system. *See, e.g.*, NGC Instrument Guide v.1 p. 188 ("Each module has an alignment pin on the back to ensure that it aligns correctly with the main communication board."); *see also* Fig. 39(a). The main communication board, shown in Figure 39(b) above, connects to the master control unit, shown in Figure 55 above, via a system bus that provides electrical communication to each interchangeable modular component.

58. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 3 of the '718 patent

59. Because the NGC system meets all the limitations of Claim 3 of the '718 patent, it is my opinion that the NGC system infringes Claim 3 of the '718 patent.

D. Claim 5 of the '718 Patent.

60. Claim 5 of the '718 patent depends from Claim 1. It is my understanding that this means that all of the elements recited in Claim 5 are added to what is recited in Claim 1. As such, the bases provided above that demonstrate that the NGC system infringes Claim 1 apply equally here.

Preamble

The fluid handling system of claim 1,

Evidence of Infringement

61. The NGC system meets all the elements of Claim 1, as discussed above.

Element 5(a):

wherein the interchangeable modular components are of two or more sizes.

Evidence of Infringement

62. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the interchangeable modules of the NGC system come in two different widths: single width (approx. 8.6 cm) and double width (approx. 17.2 cm). *See, e.g.*, NGC Instrument Guide v.1 p. 18. This is further illustrated in Figure 62 below, which shows six modules, two of which are blank modules (shown here laying horizontally):

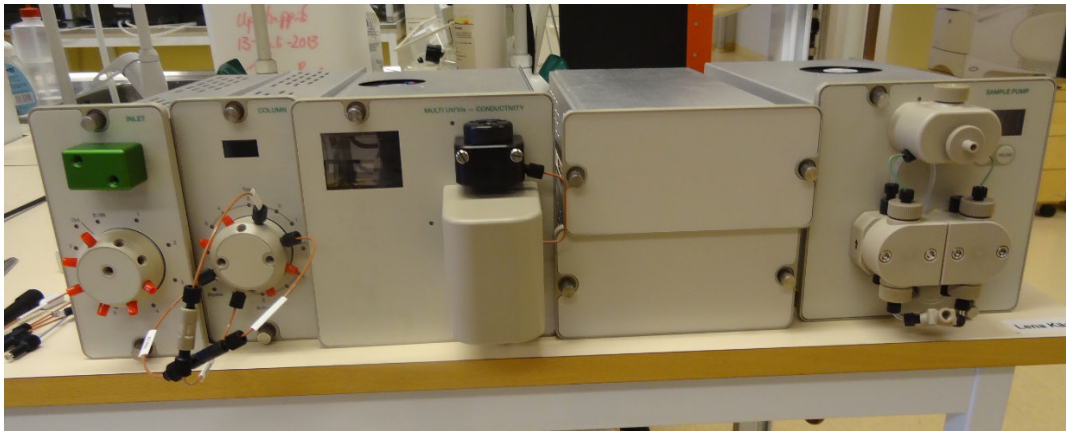


Fig. 62

The housing is configured with tracks and connectors so that a double width bay can be occupied by two single width modules. *See* Figure 39(b); NGC Instrument Guide v.1 pp. 188-189.

63. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 5 of the '718 patent

64. Because the NGC system meets all the limitations of Claim 5 of the '718 patent, it is my opinion that the NGC system infringes Claim 5 of the '718 patent.

E. Claim 11 of the '718 Patent.

65. Claim 11 of the '718 patent depends from Claim 1. It is my understanding that this means that all of the elements recited in Claim 11 are added to what is recited in Claim 1. As such, the bases provided above that demonstrate that the NGC system infringes Claim 1 apply equally here.

Preamble

The fluid handling system of claim 1,

Evidence of Infringement

66. The NGC system meets all the elements of Claim 1, as discussed above.

Element 11(a):

wherein the system is a liquid chromatography system arranged to provide a controlled fluid flow through a chromatography column.

Evidence of Infringement

67. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the NGC is a liquid chromatography system arranged to control the flow of fluid through a chromatography column. *See, e.g.*, NGC Instrument Guide v.1 p. 9 ("The NGC chromatography systems are preparative systems designed to rapidly automate the purification of biomolecules."); *id.* p. 23 (diagram showing a fluid circuit including a chromatography column). The pumps included in the NGC system

precisely control the flow rates of the liquids to avoid overpressure and deliver continuous flow with low pulsation. *See id.* at 24, 26.

68. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 11 of the '718 patent

Because the NGC system meets all the limitations of Claim 11 of the '718 patent, it is my opinion that the NGC system infringes Claim 11 of the '718 patent.

F. Claim 14 of the '718 Patent.

69. Claim 14 of the '718 patent depends from Claim 1. It is my understanding that this means that all of the elements recited in Claim 14 are added to what is recited in Claim 1. As such, the bases provided above that demonstrate that the NGC system infringes Claim 1 apply equally here.

Preamble

The fluid handling system according to claim 1,

Evidence of Infringement

70. The NGC system meets all the elements of Claim 1, as discussed above.

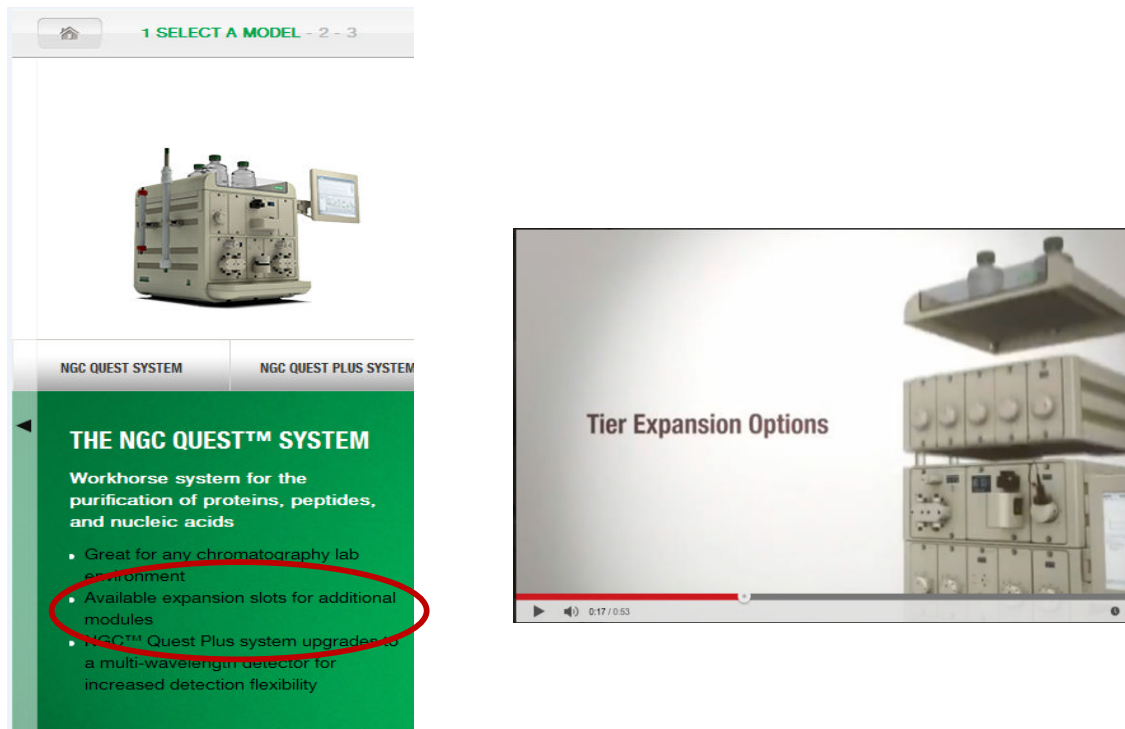
Element 14(a):

wherein the system further comprises at least one expansion housing module for accommodating additional interchangeable modular components.

Evidence of Infringement

71. I have reviewed Bio-Rad's instructional and marketing materials and I have determined that Bio-Rad markets and sells an expansion housing module for the NGC system. Images from an "NGC System Tour" available on Bio-Rad's website (available at <http://biorad-ads.com/ngc-interactive-demo/>) show that the NGC system offers expansion slots or tiers for

additional interchangeable modular components. *See also* NGC Chromatography Systems Module Selection Guide at 2. These images are reproduced below.



Figs. 71(a) and 71(b)

72. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 14 of the '718 patent

73. Because the NGC system meets all the limitations of Claim 14 of the '718 patent, it is my opinion that the NGC system infringes Claim 14 of the '718 patent.

G. Claim 16 of the '718 Patent

74. Claim 16 of the '718 patent is an independent claim.

Preamble

A liquid chromatography system

Evidence of Infringement

75. I have reviewed Bio-Rad's instructional and marketing materials, which show that the NGC system is a liquid chromatography system. *See, e.g.*, NGC Instrument Guide v.1 p. 9. This is consistent with my inspection of the system.

76. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(a):

arranged to provide a controlled fluid flow through a chromatography column,

Evidence of Infringement

77. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined, as explained above for claim 11, that the system is arranged to provide a controlled fluid flow through a chromatography column. *See, e.g.*, NGC Instrument Guide v.1 p. 23. The pumps included in the NGC system precisely control the flow rates of the liquids to avoid overpressure and deliver continuous flow with low pulsation. *See id.* at 24, 26.

78. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(b):

the system comprising a housing and two or more interchangeable fluid handling units, the housing comprising a liquid handling panel including two or more component positions for receiving said interchangeable units,

Evidence of Infringement

79. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the NGC system comprises a housing that has bays into which two or more modular fluid handling units are inserted. *See, e.g.*, NGC

Instrument Guide v.1 p. 15 (“The modular components slide into slots in the system known as bays.”); *id.* p. 18 (showing the housing and multiple modular fluid handling units).

80. The housing includes a “liquid handling panel,” which is the front panel of the bays in the housing of the NGC system. *See, e.g.*, Fig. 42; NGC Instrument Guide v.1 at pp. 18, 187-190. The bays define various component positions for receiving the modular fluid handling units/modular components. For example, the modular components of the NGC system include a system pump, a conductivity monitor, a UV detector, an inject valve, a mixer, and a sample inlet valve. *See id.* at p. 19, 33, 51. These modular components are fluid handling units because fluid flows through the external fluidics section of each module. *See, e.g.*, NGC Chromatography Systems Module Selection Guide p. 4 (NGC system capabilities schematic showing fluid flow through various modules, including system pumps), p. 8 (showing fluid flow through UV detector module and conductivity monitor); NGC Instrument Guide v.1 p. 23 (showing fluid flow through various modules, including inject valve, conductivity monitor, and system pumps), p. 51 (explaining that the mixer is located between two system pumps so that flow from the pumps enters and exits the mixer).

81. The modular fluid handling units/modular components are interchangeable. *See, e.g.*, NGC Instrument Guide v.1 at p. 15. (“The position of each module on the system can be changed to optimize the placement and minimize the length of tubing, reducing the system swept volume.”).

82. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(c):

wherein said units are arranged as interchangeable modular components, and include:

Evidence of Infringement

83. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the liquid handling units of the NGC system are modular components that slide into the bays of the housing. *See, e.g.*, NGC Instrument Guide v.1 at p. 15 ("The modular components slide into slots in the system known as bays."). The illustration of the housing of the NGC system shows the principle of interchangeable modules fitting into bays. *See, e.g., id.* at p. 186; *see also* Fig. 35 above.

84. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(d):

a fluidics section;

Evidence of Infringement

85. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include fluidics connections for various components that include fluidics on the outside of the respective panels of each component. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74. For example, the NGC system has two system pumps, a UV detector/conductivity monitor, and a sample pump that are interchangeable modular components and which contain fluidics sections on the exterior portion of the module. *See id.* pp. 18-19, 24-25, 54-61; *see also* Fig. 62 above.

86. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(e):

a non fluidics section in turn comprising electronics or electrical components or control means; and

Evidence of Infringement

87. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include a non fluidics section of electronics or electrical components on the side of the modular component that is inserted into the bay. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74, 186. The back of each module has electronics and electrical components that plug into the housing. *See* Fig. 39(a) above. The alignment post next to each of the electronics and electrical components (shown in Figure 39(a) above) aligns the electronics and electrical components with receptacles in the housing (shown in Figure 39(b) above). *See also* NGC Instrument Guide v.1 pp. 188-189. This illustrates that the electronics and electrical components are on the side of the modular component that is inserted into the bay (as opposed to the front-facing side which contains the fluidics section -- *see, e.g.* Fig. 41).

88. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(f):

a panel member arranged to separate the fluidics section from the non fluidics section and for attachment of the modular component to a component position of the liquid handling panel,

Evidence of Infringement

89. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components of the NGC system include a panel that separates the external fluidics section from the internal non fluidics section. *See, e.g.*, NGC Instrument Guide v.1 pp. 19-74, 186. Specifically, each NGC module is provided with a front facing physical barrier that provides a separation between the external

fluidics and the internal non-fluidics components of the modular component. *See, e.g.*, Fig. 41; *see also* NGC Instrument Guide v.1 p. 188.

90. The panel member also provides for attachment of the modular component to the liquid handling panel. Specifically, the panel member contains a screw or screws (shown in Figure 41) which, when tightened, attach the modular component to the liquid handling panel (shown in Figure 42). *See also* NGC Instrument Guide v.1 pp. 187-188.

91. Thus, I have concluded that the NGC system satisfies this claim element.

Element 16(g):

and wherein the liquid handling panel of the housing and the panel members are arranged such that the fluidics sections are external to the housing and respective non fluidics sections are internal to the housing.

Evidence of Infringement

92. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and, as explained above, I have determined that the liquid handling panel of the housing (*see, e.g.*, Fig. 42) and the panel members (*see, e.g.*, Fig. 41) are arranged such that the panel member, when attached to the liquid handling panel by means of the screw or screws (*see, e.g.* Fig. 41), separates the respective fluidics sections from the non fluidics sections. The fluidics sections are external to the housing (*see, e.g.*, Fig. 41), while the non fluidics sections are internal to the housing (*see, e.g.*, Figs. 39(a) & 39(b)). *See also* NGC Instrument Guide v.1 pp. 186-191.

93. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 16 of the '718 patent

94. Because the NGC system meets all the limitations of Claim 16 of the '718 patent, it is my opinion that the NGC system infringes Claim 16 of the '718 patent.

H. Claim 17 of the '718 Patent.

95. Claim 17 of the '718 patent depends from Claim 16. It is my understanding that this means that all of the elements recited in Claim 17 are added to what is recited in Claim 16. As such, the bases provided above that demonstrate that the NGC system infringes Claim 16 apply equally here.

Preamble

The liquid chromatography system according to claim 16,

Evidence of Infringement

96. The NGC system meets all the elements of Claim 16, as discussed above.

Element 17(a):

wherein the interchangeable modular components include at least one of: an injection valve; a column valve with integrated pressure sensors; a conductivity monitor; a UV monitor; a quaternary valve; an inlet valve with integrated air sensor; a system pump; a pump pressure monitor; an inlet valve with integrated air sensor; a rising valve; a mixer; a filter; a sample inlet valve; a flow restrictor; a pH valve; and outlet valve; and a dummy component.

Evidence of Infringement

97. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the following modular components are available for the NGC system: a column valve with integrated pressure sensors; a conductivity monitor; a UV detector; an inject valve; a system pump; a mixer; a sample inlet valve; a pH

valve, an outlet valve, a buffer blending valve (which is a quaternary valve), and a blank module (which is a dummy component). *See, e.g.*, NGC Instrument Guide v.1 pp. 19-76; *see also* Fig.

62.

98. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 17 of the '718 patent

Because the NGC system meets all the limitations of Claim 17 of the '718 patent, it is my opinion that the NGC system infringes Claim 17 of the '718 patent.

I. Claim 18 of the '718 Patent.

99. Claim 18 of the '718 patent depends from Claim 17, which in turn depends from Claim 16. It is my understanding that this means that all of the elements recited in Claim 18 are added to what is recited in Claim 17 and Claim 16. As such, the bases provided above that demonstrate that the NGC system infringes Claims 16 and 17 apply equally here.

Preamble

The liquid chromatography system according to claim 17,

Evidence of Infringement

100. The NGC system meets all the elements of Claim 17 as discussed above.

Element 18(a):

wherein said modular components are interconnected fluidically on the external side of the panel.

Evidence of Infringement

101. I have reviewed Bio-Rad's instructional and marketing materials, and I have inspected the NGC system, and I have determined that the modular components are connected by tubes so as to allow the flow of fluid on the external side of the panel. *See, e.g.*, NGC Instrument

Guide v.1 pp. 23. In my inspection of the NGC system, I determined that the fluidics connections are made using PEEK tubing (internal diameter: 0.020-0.030 inches) with plastic fittings. This is further illustrated in Figure 101 below:

*Modular components
connected by tubes (or
“capillaries”)
carrying fluids*



Fig. 101

102. Thus, I have concluded that the NGC system satisfies this claim element.

Summary of Claim 18 of the '718 patent

103. Because the NGC system meets all the limitations of Claim 18 of the '718 patent, it is my opinion that the NGC system infringes Claim 18 of the '718 patent.

104. Thus, I believe that the NGC system meets all of the limitations of Claims 1, 2, 3, 5, 11, 14, 16, 17, and 18 of the '718 patent. Even if Bio-Rad could somehow show that any claim limitation is not literally present in the NGC system (with which I disagree), it is my opinion that the limitation would nevertheless be met under the doctrine of equivalents. Indeed, any difference in any element in the Bio-Rad system and the corresponding claim limitation, as

discussed above, would be insubstantial and would perform at the very least substantially the same function, in substantially the same way, to achieve substantially the same result.

Dated: September 9, 2014

Carl Scandella
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